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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John G. Babish, et al.

Application No.:

10/789,814

Filing Date:

February 27, 2004

Docket Number:

068911-0075

Title:

SYNERGISTIC ANTI-INFLAMMATORY

PHARMACEUTICAL COMPOSITIONS AND METHODS

OF USE

Examiner:

Shobha Kantamneni

Art Unit:

1617

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Date: 08/07/06

Angelo I Mignanelli ERIN M. Olson

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir:

DECLARATION PURSUANT TO 37 C.F.R. § 1.131

I, John G. Babish declare as follows:

1) I am Dr. John G. Babish, Executive Vice President of Metaproteomics, LLC. I have held this position since August 2002.

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- 2) I have Doctorate and Masters degrees, respectively, in Biochemistry and Chemistry from Cornell University, as well as a Bachelor degree in Biochemistry from The Pennsylvania State University. A copy of my Curriculum Vitae is attached as Exhibit A.
- 3) I am also an inventor named in several domestic and foreign patent applications including U.S. Application Nos. 10/141,085; 10/789,814; 10/789,817; 10/988,393; 10/480,145; 10/484,123; 10/881,404; 10/774,048; 10/464,834; 10/234,002 and 09/952,632 and issued foreign and domestic patents, including U.S. Patent Nos. 6,140,063; 5,506,420; 6,629,835; 6,733,793 and 6,908,630.
- On the basis of 30 years of training and experience, I am an expert in the art of molecular biology, more specifically, that aspect of molecular biology involving signal transduction. I was a faculty member at the College of Veterinary Medicine, Cornell University for 17 years. As Professor of Pharmacology and Toxicology, my research program involved the elucidation of mechanisms by which xenobiotics affect signaling pathways in normal and transformed cells. Using the tools of molecular biology such as monoclonal antibodies, northern and western blotting and enzyme-linked immunoassays, my research program developed cell-based assays for the identification of small molecules directed at inhibiting selected cellular functions. Findings from these studies were used to identify potential anti-viral and anti-neoplastic pharmacophores from natural products. My research has also identified both positive and negative drug-drug and drug-nutrient interactions.
- 5) I understand that in the course of the February 7, 2006 Office Action during prosecution in the above-captioned application, Examiner Shobha Kantamneni rejected claims 1 7 under 35 U.S.C.§ 103(a), as allegedly being unpatentable over Kuhrts (US 2004/0137096, PTO-892) for reasons of obviousness. I respectfully submit that the instant invention was conceived prior to the January 9, 2003 filing date of the cited Kuhrts application and diligently researched until the February 27, 2004.

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The basis to assert that the instant invention was invented prior to the Kuhrts reference cited is supported by copies of laboratory notebook pages dated from June 2002 through December 2003 showing research on the synergistic, anti-inflammatory effects of reduced isoalpha acids (RIAA) and isoalpha acids (IAA). Such support documentation is appended herewith as Exhibit B.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 5-14-06

John G. Babish, Ph.D. Executive Vice President

Metagenics Research Center - Suite 100

9770 44th Ave. NW Gig Harbor, WA 98332

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Exhibit A BIOGRAPHICAL SKETCH AND BIBLIOGRAPHY

John G. Babish

Chariperson, BIOnexus, Ltd.

Executive Vice President, Metaproteomics Inc.

Education

Institution and	Degree	Date Conferred	Field
Location of Study The Pennsylvania	B.S	1968	Biochemistry
State University, State College, PA			
Cornell University, Ithaca, NY	M.S	1974	Chemistry
Cornell University, Ithaca, NY	Ph.D.	1976	Biochemistry

Reseach and Professional Experience

Aug. 2002 - present Executive Vice President of Research & Development, Metaproteomics, Research Laboratories, Ithaca. NY. Metaproteomics develops clinically proven, patented dietary supplements and pharmaceuticals from natural sources. Duties include the design and evaluation of experiments elucidating mechanism of action and biological activity within complex mixtures.

1998 – present

(5% Effort) National Coordinator for the USDA Minor Species Drug Program (NRSP-7). The NRSP-7 program is funded by the USDA to provide funds and expertise necessary for the approval of pharmaccuticals used in the treatment of diseases associated with minor crop species. Duties include the coordination of industrial. academic and regulatory resources necessary for protocol development through final drug approval.

1997 - present

Co-founder and Chairperson of BIOnexus, Ltd. Ithaca, NY. BIOnexus develops and markets nutritional supplements to address health problems associated with AIDS. NutriVirtm, the BIOnexus supplement for wasting in HIV/AIDS, generated approximately \$600,000 in gross revenues in its first year of sales. NutriVirTM is reimbursed by Medicaid in 14 states.

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1991 - 1996

Founder, Chairperson, President and CEO of Paracelsian, Inc., Ithaca, NY. The Company was launched from the technology transfer program of Cornell University in 1991, and with the public offering in 1992 (Nasdaq, PRLN), became the first public corporation of a Cornell University technology transfer effort. Babish was associated with the attainment of over \$12 million dollars in corporate financing.

1984 - 1996

Tenured, Associate and Professor of Pharmacology and Toxicology, Department of Pharmacology, College of Veterinary Medicine, Cornell University. Offcred the first course in molecular risk assessment in the USA in 1979; member of the graduate Fields of Pharmacology, Toxicology, Veterinary Medicine, Food Science and Epidemiology; successfully petitioned the State of New York for the approval of the separate Fields of Toxicology and Pharmacology at Cornell University.

1978 - 1984

Assistant Professor, Department of Preventive Medicine, NYS College of Veterinary Medicine, Cornell University, Ithaca, NY.

1976 - 1978

Postdoctoral Scientist, Food and Drug Research Labs, Waverly, NY.

Invited Presentations (Recent of 38 presentations)

Micronutrient deficiencies in AIDS wasting at Progressive Management of AIDS Wasting: 2000. Hunter College, NYC. March 24, 2000.

Phytochemicals and NF-kB activation at IBC's Conference on The Health Benefits of Natural Phytoceuticals. Montreal Bonaventure Hilton, July 22 – 23, 1997.

Chemically-induced cell cycle stasis in immunotoxicology. 12^{th} Annual NIOSH Conference on Mechanisms of Immunotoxicology — Role of Apoptosis in Immunotoxicology. University of West Virginia, Morgantown, WV. September 10-12, 1997.

Publications (Selected of 108 peer-reviewed publications)

Payne M.A., Babish J.G., Bulgin M., Lane M., Wetzlich S., Craigmill A.L. (2002) Serum pharmacokinetics and tissue and milk residues of oxytetracycline in goats following a single intramuscular injection of a long-acting preparation and milk residues following a single subcutaneous injection. J Vet Pharmacol Ther. 25(1):25-32.

Calabrese C., Berman S.H., Babish J.G., et al. (2000) A phase I trial of andrographolide in HIV positive patients and normal volunteers. Phytother Res. 14(5):333-338.

Ma,X., Stoffregen,D.A., Wheelock,G.D., Rininger,J.A. and Babish,J.G. (1997) Discordant hepatic expression of the cell division control enzyme p34cdc2 kinase, proliferating cell nuclear antigen, p53 tumor suppressor protein, and p21Waf1 cyclin-

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John G. Babish, et al.
1.132 Declaration of John G. Babish
Page 6 of 7

dependent kinase inhibitory protein after WY14,643 ([4-chloro-6-(2,3-xylidino)-2-pyrimidinylthio]acetic acid) dosing to rats. Mol. Pharmacol., 51, 69-78.

Rininger, J.A., Goldsworthy, T.L. and Babish, J.G. (1997) Time course comparison of cell-cycle protein expression following partial hepatectomy and WY14,643-induced hepatic cell proliferation in F344 rats. Carcinogenesis, 18, 935-941.

Rininger, J.A., Stoffregen, D.A. and Babish, J.G. (1997) Murine hepatic p53, RB, and CDK inhibitory protein expression following acute 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) exposure. Chemosphere, 34, 1557-1568.

Rininger, J.A., Wheelock, G.D., Ma, X. and Babish, J.G. (1996) Discordant expression of the cyclin-dependent kinases and cyclins in rat liver following acute administration of the hepatocarcinogen [4-chloro-6-(2,3-xylidino)-2-pyrimidinylthio] acetic acid (WY14,643). Biochem. Pharmacol., 52, 1749-1755.

Vancutsem, P.M. and Babish, J.G. (1996) In vitro and in vivo study of the effects of enrofloxacin on hepatic cytochrome P-450. Potential for drug interactions. Vet. Hum. Toxicol., 38, 254-259.

Patents (Selected of 15 US and three foreign patents)

US Patent No. 5,833,994	11/10/1998 Use of the Ah receptor and Ah receptor ligands
	to treat or prevent cytopathicity of viral infection.
US Patent No. 5,612,188	3/18/1997 Automated, multicompartmental cell culture
system.	·
US Patent No. 5,529,899	6/25/1996 Immunoassay for Ah receptor transformed by dioxin-like compounds.
US Patent No. 5,496,703	3/5/1996 Indirect immunoassay for dioxin-like compounds

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Page 7 of 7

Exhibit B

LABORATORY NOTEBOOK SHEETS DOCUMENTING RESEARCH ON RIAA, IAA AND OTHER HOPS DERIVATIVES

Date	Notebook Number	Pages
6/4/02 - 6/24/02	2002-03	13 - 23
8/28/02	2002-04	3-4
12/5/02	2002-06	1-2
3/5/03	2002-06	43 - 44
4/23/03	2003-01	23
6/5/03	2003-01	45
9/3/03	2003-4	22
12/15/03	2003-5	42

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1. BetsTech - Alpha hop (10μg/pL)	The second of th	111 Studies Ab Wals	- Campound D.	:
2. BetaTech - Beta ecid solution (10)(0)(L)	Alpha hop = 50.000 10.000 5.0	00 1,000 a	a on these tox	צָי
3. BetsTech Aromatico (E (10)g/pL)	Bein said solution = 50,060 10,000 5.0	1.000 8 . 17 (4 H	es she identical.	
4. BetaTech (sohop (IAA) (10µg/µL)	Aromahop (100 = 50.000 10,000 5,00 5,00 500 500 500 500 500 500	" "	- amount or	
5. BetaTech Redinep (RIAA) (10µgA£)		1 14 4		:
6. Belatech Tetrahop Gold (10µg/4.)	Tetrahop Gata = 50,000 10,000 5.00		emodinie (FCICI)	٠
7. BetsTech Herahop gold (HHAA) (10µgApL)	Hexahop gold = 60.000 10;000 8.00	1256	als at	!
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2. SetulToxin - Sata sold solution (10pg/pL)	Alpha hap = \$0,000 10,000 5.00 Beta cold solution = \$0,000 10,000 6.00	"!!!		:
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6. BetaTech Tetrahop Cold (10pg/yL)	Telrahop Gold = 50,000 10,000 5,000	, ,		: }
7. BetaTech Hesshop gold (HHAA) (1000/UL)	Herahop gold = 50,000 10,000 5,000			.
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Cleanote add 80% - Sebinsa Ctranote add 80% = 50.00 B. Bata Tech Radhop (RIAA) (10)ppl.) Radhop (RIAA) = 50.00 Curcumin granutar (06896) Curcumin = 50.00	5.000	0.800 0.050 0.050 0.500 0.050	8	
7. RIAA-t/melic add (90%) - (1:1) Total = 50,00 RIAA = 25,00 Ursofta add 90% = 25,00 Ursofta add 90% = 50,000 Riagna = 50,000	5.000 2.500 3.500	0.500 0.050 0.250 0.025 0.250 0.025	8	
9. Celebras Celebras 5,000 10. Aughlin - Gigma Asphin = 50,000	1 1	0.050 0.005 8.000 1.000 lotal =	8 8 80	
2_CoxL1RAM_8_34.co		· · ·		
PGE2 assay, using undiluded and 1:1 dilution from the plates 5.24,02 (1994) RAW 354.7 cells no LFB attractions and 60 min with 100 (AR ARA) Grap pour is the little of the plate of the pl	:	0.500 0.050	8	
2, Limanite acid 80% - Babinsa 80,000 3. Cermonia acid (Rosementy) 90,000 4. Cileanolio acid 60% - Babinsa 50,000	5.000	0.500 0.050 : 0.500 0.050 :	5 5	
5. Bata Tech Radilhop (RIAA) (10\(\frac{1}{2}\)\(\f	1.000 1.000	0.500 0.050 0.500 0.050 0.500 0.050 0.500 0.025	8	
Uracitic acid 60% = 25,000	2.500 5.000	0.280 0.025 0.600 0.050	8	
10. Apptin - Sigme Acptin = \$0,000	10.000	5.000 1,000 total =	80	
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General 6.24	ate		Signed	7-19-02 Date

sion in Alst	A-549 Collection	ook No.	55 -0,3
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	71 (0) 1.		
C2_COX2_ASIE			
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and dilated 120.	or positions assessment for PGE2.		
Breaten (RAN) = 25			
Total # 25 IAA = 12,5	60 0.3 0.06	2	smounds a
FAA = 12,8	2.3 0.25 0.028	S. n. Col	se 708 th
IAA# 18.7 RIAA E AS	3.3 0,333 0,033 1.7 0,187 0,017	· note Go	,(라 _
Total = 26	. 5 0.6 0.06 (4.2 0.417 0.042		
Total = 28	e de one		
RIAA 23	4,65 g0.4545 0.0148 0,43 0,0453 0,0045		
Total = 28 IAA = 24,5 RIAA = 0,8	8 0,5 0,68 8 4,90 0,490 0,049 0,10 0,010 0,004		
Tatal = 28	:0 10.8 0.06 m		
. RAA = 0.26	ayda grosso g'0000		
IAA R . 12.5 Tryptantists = 12.5	2.5 0.25 0.025 2.6 0.25 0.025 2.6 0.25 0.025		
::	Total = 72		
Service of the servic		-	
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is the ted	The same	45 the	okta on
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A64R_8.28.828TD6			
shed, test materials added for 60 minutes	then Azzier (50 uM) added an	Aldrey Tol2	44
: 1	2-	ANVOCE	معد المعدد
	8-	· · · · · · · · · · · · · · · · · · ·	-
25 5.0 0.8	0.05 B	1 1 1 1 1 7	HITHIC
25 3.0 0.5	0.05		· 1 · 1 · 1 · 7
20 50 05		7 - 4843	164 56H 13
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25 5.0 0.5	0.05	A 5376 to	ここるもつし
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25 5.0 0.5	0.00	W182863 6	st 11/2/176
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8.28.01	- DZG(2-	9-1-0
4.74 0) Date	Signed	2	9-1-0 Date
	C2_COX2_ASES In main implicated, informational with it. Vic.PSBPCOX21 in main distribution of with it. Vic.PSBPCOX21 in main distribution of 120. Description (RAA) = 25 From = 25 From = 26 FRAA = 42.6 FRAA = 42.6 FRAA = 42.6 FRAA = 42.7 FRAA = 0.3	A	C2 COC2 ANS BERGE TO A 21 6.0 0.0 0.00 0.00 0.00 0.00 0.00 0.00

PROJECT REE	Emprosition	مند	A-54	: 	65 Cells	Not	tebook No	2-04
AGS Calls Formal A - wesh, add trat main	riel and assay for PGE2 (he	next eley						
For POE2 assay on made undired 8-3-s-2				i			Experiment)	202-57-01
1. Oleanollo acid (BO% Sebinse)	Oleanofia acid	. 25	5,0	A.O	0.05	0		
2. BelsTech (RIAA)	BHATTER (RIAA)	- 25	3.0	فه	0.05			
3. Tryptenindo - Wason Chemicals	Tryptanshrin	- 10	1	0,1	QD1			
4. RIAA:Oteanolin ecit - [10:1]	Total	- 25	5	 ويْدە	0.05		*	
	RIAA Oléandia		4,5 0.5	0.455 0,645	0,045 0,005			
6, RIAA:Cleanotic acid - [5:1]	Total RIAA	- 28 - 20,6	· 6 42	: 0.5 0.417	0.05 0.042	•	The Arst	tevo
6. RIAA:Oteanolic setd - [1:5]	Cite nois Total RAA	= 25	0.8 · 5	0.063 0,5	0.006 0.06	e .	plates we	ne nen
	Oleanolla	•	:	•			in the e	THE THE
7. RIAA;CHeanolfo acid - (1:10)	Total RIAA	25	5	0.5	0.05	8	544 1 100	الم ما ما ما ما
	Oleanoile			•		• •		nner 49
8. #1115 Metogeratos	#1113	- 25	5	0.8	8.05	Δ	17 may -54	1 04+B
9, Rissattriplantain - [121]	Total RIAA		- 5	0.6	£ 0,05		Fort Ward on	7
	Tryptanthin				*********			Y CANAL STATE
Run 1000, 500, 15.6 and 7.6 coordinations of t	Itm standard rumm no contro	Column 2			Total =	72	ma Tures	· 1047417
AGS Cells Formet A - temb, and heat material and . For PGS2 many run media undished 8.68.02			· ' 1	1 .)			notebook	
						}		
4 Berts Took (SAR)	PA = 23	. 6.0	0.5	0.05	SAN CONTRACTOR			
T. DateTouch (FLIAA)	BetaTech (RIAA) = 28	0.0	0.5	0.05				
S. MARIAA (1:3)	7000 > 25 VA = 125 RIAA # 123	2.5 2.5	0.8 0.25 0.25	0.035 0.035		.,		
4. MASIAA - (2:1)	Total = 25 IAA = 18.7 RIAA = 1.3	8 83 1.7	0.8 6:333 0;187	0.06 ¹ 0.033 0.017	•	[.		
6. MA:RMA - (8:1)	Total = 2s MA = 20s RIAA = 42	8 4.2 0.1	0.6 0.417 0.063	0.000 0.043 0.02 :		_	V	
8, 1842/544 - (10:1)	Total = 23 IAA = 227 RIAA = 23	4.65 0.46	0.8 0.4545 4.0455	0.06 0.0458	•			
7. MASHAA - [50/1]	Total v 23 IAA v 24.6	. i 5	0.5 0.450 0.010	0.05 0.05 0.09 0.001	•		
& IAARIAA -[TOR1)	PLAA = 0.5 Tirbs = 25 IAA = 34.76 PLAA = 0.35	0.10 4.88	0.010 0.4 0.4860	0.001 0.05 0.0496		• • • • • • • •		
9. IAATiyytsolisti = [1:1]	704 - 036 144 - 128	0.05 2.6	0.0000 0.0 0.25	0.0006	•		, , ,	
	Trypiensadn v 126	25	0.25	0.025 0.025 Toles =	72	• • •		
Run 1000, 800, 15,5 and 7,8 equivariations of the times	440 curve as series in Casuma 2	<u>: </u>				1	
AGS Calls - calls grown to confliverice, wash, t assay for PGE2 30 mineries later. For PGE2 sasey run media undilated and 1/29 a.bel.be	test exeterials added for 88 (ninutes (h	m, A23187 (56 p	el() edded and :	a	P	late to	donain
							the test	
1. Disopropyl Suorophosphate	cox-s	25	5.0	0.3	0.03 0			Hericus
2. Work	cox-s	25	S.d	0.5	0,05 B	6	zakea and	True (
7. Calebrax	00X-3	25	6.0	5.5	0.05 A		minutes tel	thou
C Nimenaulide	COX-2	25	5.0	es ;	0.96 a		الم صم	
5. Ibuproten	C000-2/0000-1	25	.6.0	0.5	0.05 8	1	السراد عبيب	41cl 4
J. Indomeliach	COX-1	25	5, 0	0.5	0.95 6		A 23167 45	+ 30 min
7. Aspirin	COX-1	25	5.0	05 .	P. 93 8		Bacon of	Lees Ash
3. Salityfic acid	•	25	5.0	0,5	0,08 6 :	-	7	577
). Heproxon	•	25	5.0	9.6	D.016 8	ļ	40h 1005	Milles
О. Авекания ордин	•	25	5.0	0.5	0.60 S Telat= 80	. !		
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		COXAGS ISAMAS	Des 2 - 0 a - 43	
	AGS Cells -cells grown to confluence, week, but materials as example: PGE2 30 collectes later; For PGE2 easey run med9 diluted 1:20 only	point for 60 minutes then A23187	(BO UM) added and	
	3.03.01 Compound Commo	di di di	[65 64 77	
	1. Utzahritanenko ingredienta	da co	0.5 0.05 8	}
	2. META581	80 5.0	D.S. 0.05 &	
1	3 Rommery extract (07720)	50 5.0	0.5 0.06 8	.
	4. Clasmolic acid (80% Sabinsa)	50 5.0	8 20.0 2.0	
	5. RIAA (Huss) 6. Rufin (08284)	50 5.0 50 5.0	0.5 0.05 8	
	7. Gureumin (07367)	50 5.0	as aps 8	
	6. Glinger mot (06936)	50 5.0	0.5 0.08 s	
	9. Al-Ea	50 5.0	0.5 0,05 B	i
	10. Aspirin (Stame)	. sp 5.0	0.6 0.06 8	. !
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	AGS Calls - calls provin to confiturios, week, seel meter es ser for PGEZ ab estratios letter. For PGEZ aberry run media diluted 1:20 anity 3:03,09 [Chrispound C. I. Isohop AN1127 2. 81115 3. Tetrahop AN1120 4. Hamshop AN1120 6. Alphahop AN1126 6. BetaStaty AN1126 7. Iso-Rich AN1090 8. Tempo Estract #4411 AN1173 9. A70 LIPOTECN 10. Anomahop AN1126	Commonds (sq./mt.) (sq./mt.) (sq./mt.) (sq./mt.)	63	
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Composes 15 20 20 20 20 20 20 20 2	AJ 0.05 and Calls - calls grow as a call calls for PGE2 38 mm above a call for PGE2 38 mm and provided for PGE2 38 mm and provided for PGE2 38 says rule on the call of the ca	wn to continuence, was inutes buter,	th, fuel materials added for 80 minutes then AZ3167 [68 pM] added and	
RIAA - E-IBB - GAB Agains - GE, pp - 4,80	0.med 10m 4.E1.D3	- 1.20 Billy	81 d2 d3 d4	
	Compound 1. Isohop AN1127	 	<u> Соримента - Бирина (уорина) Бурина Бурина (уорина)</u> 60 8.0 4.6 0.06 8	
	2.61115		50 5.0 Q.5 Q.25 B	
	a. Tetrahop AN1120		50 5.0 0.5 0.05 B	
	4. Hoxeliop AN1130 3. Alcherop AN1124	-	50 5.0 a.5 0.05 B	
	5. Agriance AN1128 6. BelaBlad AN1125		50 5.0 0.5 0,05 8 . 50 5.0 0.5 0,05 8	
	7, Iso-Rich AN1090		50 5.0 0.6 0.08 8	
	6. Tunnin Extract #441	T AN1175	50 5.0 0.5 0.05 8	
	E ATO LIPOTECH		50 5.0 0.6 0.05 8	
	10. Arametrop AN1126		50 5.0 as 9.05 s	
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